62. These statements were knowingly and demonstrably untrue when made. Defendant did not introduce new studies because it wanted to avoid the likelihood that additional adverse information would come to light.

63. Each of the statements made from January 2002 through December 2002 concerning VIOXX® was materially false and misleading when made, because each statement failed to disclose material facts needed to make the statements made not misleading in light of the circumstances under which they were made. In fact, Defendant knew that VIOXX® was associated with a significant risk of cardiac events. The true but concealed and/or misrepresented facts included, but were not limited to:

- At the time of the FDA's February 2001 Advisory Committee meeting, the Merck Defendant were aware of the cardiovascular risks associated with VIOXX®, and were aware that VIOXX® did not have an excellent safety profile;

- Merck's press releases "reconfirming the favorable cardiovascular safety profile of VIOXX®" during 2002 were unfounded, because the Merck Defendant knew that VIOXX® was associated with high cardiovascular risks;

- Merck's announcements refuting the Cleveland Clinic study results in *JAMA* and stating that the Company stood behind the safety profile of VIOXX® were unfounded, as the Merck Defendant were aware that VIOXX® in fact caused an increase in adverse cardiovascular events;

- The Revised label for VIOXX® that Merck announced in April 2002 failed to disclose the severe cardiovascular risks that the Merck Defendant had already observed in, among other things, Study 090 and VIGOR;

- The VIOXX® promotional activities that the FDA condemned in the September 17, 2001 FDA Letter stemmed from Merck Defendant' deliberate efforts to conceal VIOXX®'s known risks, which continued in 2002;

- Merck's unpublished Study 090 concluded that VIOXX® users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

- Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved VIOXX® for prescription use, Merck knew of the VIOXX®-related medical risks;

> findings. "Randomized clinical trials are the gold standard and this isn't such a trial," said Alise Reicin, Merck's executive director of clinical research. "In our placebo-controlled randomized trials, we have found no significant difference between Vioxx and placebo."

Defendant's comments were directly contradicted by Merck Internal documents, e-mails and materials, and Merck's own studies.

66. Continuing their aggressive campaign to suppress the truth about VIOXX®, Defendant acted quickly to assure it's consumers that VIOXX® was safe. On November 5, 2003, The Wall Street Journal published a Letter to the Editor by Defendant, (the "November 5, 2003 Wall Street Journal letter") entitled "Merck Stands Behind the Safety of Vioxx." In the November 5, 2003 Wall Street Journal letter, Defendant made, among others, the following materially false and misleading representations and/or omissions of material fact:

> Nothing is more important to Merck than the safety of its medicines. Your Oct. 30th story about an observational analysis of Vioxx was incomplete. The article discussed only the findings from this analysis where Vioxx appeared to have an unfavorable risk profile, but failed to report other findings from the same analysis that showed no statistically significant difference in the risk of heart attack for Vioxx compared with other commonly used anti-inflammatory drugs.
>
> The story also failed to report that another observational analysis presented at the same scientific meeting also showed no statistically significant difference in heart attacks between Vioxx and two widely used anti-inflammatory drugs, ibuprofen and diclofenac. *A complete reporting of the data presented might have remedied the mistaken impression left by the story.*
>
> Observational methods lack the rigor of randomized, controlled clinical trials, and have led the scientific community astray before. That is why observational studies must be interpreted with caution. *Merck stands behind the safety of Vioxx based on the results of numerous randomized, controlled clinical trials.*

The November 5, 2003 Wall Street Journal Letter failed to disclose what Defendants Kim and Merck knew: that VIOXX® was in fact associated with serious cardiovascular risks. More

specifically, Defendant had long before concluded that VIOXX® actually caused severely negative cardiovascular events -- a fact confirmed in internal Merck materials.

67. Each of the statements made from January 2003 through December 2003 concerning VIOXX® was materially false and misleading when made, because each statement failed to disclose the extent of the Defendant's knowledge that VIOXX® was in fact associated with a significant risk of cardiac events. The true but concealed and/or misrepresented facts included, but were not limited to:

- The Company was aware that Vioxx itself created an increased risk of heart attack, and that its explanation for the VIGOR study results--that the Vioxx patients suffered greater incidences of cardiovascular events because of cardioprotective qualities of Naproxen--was inaccurate;

- The Company's statements refuting the results of the Brigham & Women's Hospital Study finding an increased risk of heart attack in patients taking Vioxx were unfounded;

- The Company's announcements and press releases throughout 2003, stating that Merck 'stands behind the safety of Vioxx's were unfounded, because Merck knew that Vioxx, in fact, was associated with cardiovascular events and was therefore not safe;

- Merck's press releases "reconfirming the favorable cardiovascular safety profile of Vioxx" during 2003 were unfounded, because the Merck Defendants knew that Vioxx was associated with high cardiovascular risks;

- The Vioxx promotional activities that the FDA condemned in the September 17, 2001 FDA Letter stemmed from Merck Defendants' deliberate efforts to conceal Vioxx's known risks, which continued in 2003;

- Merck's unpublished Study 090 concluded that Vioxx users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

- Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved Vioxx for prescription use, Merck knew of the Vioxx-related medical risks;

- Substantial data existed in 1999 that Vioxx was associated with a higher risk of cardiovascular events than other NSAIDs; and

• On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing defendants for misleading the public by using deceptive promotional materials that suggested Vioxx had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

• Merck Defendants knew that the negative cardiovascular events were not due to the cardioprotective properties of Naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendants observed in Study 090; and

• Vioxx's safety profile was not "excellent" as the Merck Defendants claimed, but was instead marked by an unacceptably high risk of negative cardiovascular events.

F. 2004 False and Misleading Statements

68. During 2004, prior to an after taking VIOXX® off the market, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts, some of which included the following,

69. On May 18, 2004, the American Health Line published an article (the "May 18, 2004 Article") entitled "Merck: Removes Author's Name from List in Vioxx Study." The May 18, 2004 Article described how when the Harvard-Brigham & Women's Study was originally presented, the list of authors included Merck epidemiologist Dr. Carolyn Cannuscio. However, when the study was published in the online edition of the American Heart Association's journal,

***

Worldwide sales of Vioxx, Merck's arthritis and pain medicine, were $653 million for the second quarter and $1.3 billion for the first six months. U.S. mail-order-adjusted prescription levels for Vioxx decreased by 5 percent during the quarter, as compared to the second quarter of 2003.

Following FDA approval for the acute treatment of migraine in late March, Vioxx is now approved for treating more types of painful conditions than any other coxib in the United States and remains the only coxib approved to relieve migraine pain and associated migraine symptoms. Merck continues to seek new uses for Vioxx to extend the clinical benefits of the product to new populations. A supplemental NDA for Vioxx is under review by the FDA for the treatment of juvenile rheumatoid arthritis. Outside of the United States, Vioxx continues to be

> the best-selling arthritis and pain medicine. Indications for Vioxx for migraine and juvenile rheumatoid arthritis also are being sought outside of the United States.

The July 21, 2004 Press Release failed to disclose information known by Merck concerning the cardiovascular risks associated with VIOXX® and the impact of those risks and related liabilities on the medical and commercial viability of VIOXX®.

70. The May 18, 2004 Article quoted Merck spokesperson May Elizabeth Black as stating:

> Merck disagreed with the conclusions and didn't think it was appropriate to have a Merck author. Nancy Santanello, Merck executive director of epidemiology and Cannuscio's manager, said that the study had 'serious limitations' because it was 'not able to control completely for the differences between the groups.' Santanello added that Merck is currently conducting research on Vioxx and heart attacks.

The Defendant's statements were false and misleading because, among other things, it misrepresented the true facts of the Vioxx-related risks and falsely stated that Merck was conducting research on Vioxx and heart attacks.

1. Merck Publicly Discredits Results of Kaiser Permanente Study

71. On August 26, 2004, *Bloomberg News* published an article (the "August 26, 2004 Bloomberg Article") entitled "Vioxx Raises Heart Risk, Study Says; Merck disputes Tests that Favor Pfizer's Celebrex." The article stated in pertinent part:

> Merck & Co.'s Vioxx painkiller increases the chance of heart attack and death from cardiac arrest more than Pfizer Inc.'s Celebrex, according to a study by a U.S. Food and Drug Administration investigator.
>
> The difference in heart risk was statistically significant between a recommended dose of Vioxx, 25 mg a day or less, and Celebrex, according to results the FDA's David Graham presented at a meeting of the International Society for Pharmacoepidemiology in France.
>
> ***

> We found that Celebrex appears to be safer from a cardiac perspective at the lower dose, Graham said in a telephone interview from France. If there's a difference in risk between Celebrex and Vioxx, that's an important public health question, because you have two drugs being used for the same gastrointestinal effect.
>
> ***
>
> Merck disagrees with the results from Graham and his colleagues, spokeswoman Mary Elizabeth Blake said. Conclusions from that type of examination don't carry as much weight as results from a study comparing two groups of patients taking the medicines for a set period of time, she said.
>
> ***
>
> Merck researchers and officials have said the difference between Vioxx and other painkillers occurs because a comparison drug, an anti-inflammatory called Naproxen, protects the heart. The FDA funded study found the contrary--that Naproxen raises heart risk by 18 percent.

The Defendant's statements attributed were false when made in that the Defendant knew before the drug was introduced that VIOXX® caused serious cardiovascular events.

72. An article dated August 26, 2004 published by the *Associated Press* (the "First August 26, 2004 AP Article") entitled "Merck Disagrees with Vioxx Analysis," stated that [p]harmaceutical company Merck & Co. "strongly" disagreed Thursday with the conclusions of a Food and Drug Administration-funded study that said use of the company's arthritis pain reliever Vioxx increased the risk of heart attacks. At the same time, and unbeknownst to the public, Merck used all of its influence with the FDA to attempt to delay and/or thwart publication by Graham of the results of this study.

73. An article dated August 26, 2004 published by the Associated Press (the "Second August 26, 2004 AP Article") entitled "Merck Defends Arthritis Drug's Safety After Critical FDA Study," announced that "Merck shares fell 97 cents, or two percent, to $45.05 Thursday"

following the release of the FDA study results showing Vioxx's association with a high risk of cardiovascular events.

74. The Second August 26, 2004 AP Article discussed the Company's reaction to the release of the above-described FDA study:

> Pharmaceutical giant Merck & Co. insisted Thursday its blockbuster arthritis drug Vioxx is safe despite new evidence the popular pain pill increases risk of serious heart problems, even death, particularly at high doses.
>
> ***
>
> Alise Reicin, vice president of clinical research at Whitehouse Station-based Merck, said Vioxx is safe and effective, and numerous earlier studies comparing it to a dummy pill found 'no difference in the risk of having a serious cardiovascular events.' The drug was tested on about 10,000 patients before it went on sale. Reicin said the new study was not as rigorous because it was observational, rather than a controlled experiment in which randomly chosen patients get different treatments and are followed over time.
>
> ***
>
> Reicin, the Merck research executive, said half of the six observational studies on Vioxx to date found it did not increase heart complications.

Significantly, the statements attributed to Defendant all fail to disclose the significant cardiovascular risks caused by VIOXX® -- risks that Defendant was especially familiar with.

75. An article dated August 26, 2004 published by the *Associated Press* (the "Third August 26, 2004 AP Article") entitled "FDA Voices Concerns Over Arthritis Drug" quoted Defendant's analysis of the above-described study results: "Observational analyses do not have the rigor of randomized, controlled clinical trials. . . . Based on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of Vioxx." Criticism of methodology notwithstanding, Defendant's efforts to refute Graham's study were wholly unavailing because the findings were completely consistent with all of the information in Merck's files, including the results of the 1998 Study 090, the 2000 VIGOR

study, the 2001 JAMA study, the Vanderbilt UnitedHealth Care and Kemper studies and the APPROVE study which was to be terminated less than one month later.

76. On September 8, 2004, the *Dow Jones News Service* (the "September 8, 2004 article") published an article entitled: "Merck: FDA OKs Vioxx for Once-Daily Treatment of Juvenile Rheumatoid Arthritis; First and Only COX-2 Specific Inhibitor Approved for Use in Children As Young as Two." The article announced the FDA's approval of Vioxx for the treatment of juvenile rheumatoid arthritis. Merck continued to press for the FDA's approval to prescribe Vioxx for "children as young as two" despite the fact that Merck knew that Vioxx caused serious cardiovascular damage and despite the fact Merck would later withdraw Vioxx from the market during the very month which it received approval to use this deadly drug on children.

2. The Withdrawal of Vioxx and Merck's Continued Campaign of Concealment

77. On September 30, 2004, Defendant announced that it was withdrawing VIOXX® worldwide, citing as its reason the results of the APPROVe trial. However, the results of the APPROVe study were nothing new to Merck. These results were wholly consistent with studies dating back to the 1998 Study 090 and confirmatory VIGOR study in early 2000.

78. Following the announcement, Defendant continued to conceal its prior knowledge of the extent of the cardiovascular risks associated with Vioxx. For example, that same day, Defendant held a press conference to explain its decision to withdraw Vioxx. Its CEO gave the following statements:

> I'll just give you a quick summary here. The reason that we're here today is because this morning, Merck is announcing a voluntary worldwide withdrawal of Vioxx, our Cox-2 inhibitor for arthritis and pain. This decision is the result of new data from a three-year placebo controlled study which was designed to evaluate the possible use of Vioxx in

> preventing the recurrence of colon polyps. This study also collected data on the long-term cardiovascular safety of Vioxx. Importantly, in the first 18 months of the study, there was no difference in the risk for heart attack or stroke in patients taking either Vioxx or placebo. Beginning after 18 months, however, the risk of a cardiovascular event did increase among those on Vioxx.
>
> Accordingly, we are voluntarily withdrawing Vioxx effective today. We are taking this action because we believe it best serves the interest of patients. We believe it would have been possible to continue to market Vioxx with labeling that would incorporate these new data. However, given the availability of alternative therapies, and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take.

Defendant's CEO's statements were wholly false and misleading and were designed to conceal Merck's pre-1999 knowledge of Merck's cardiovascular risks.

79. On November 1, 2004, the *Wall Street Journal* published the above-described article entitled "Warning Signs: Emails Suggest Merck Knew Vioxx's Dangers at Early Stage; As Heart-Risk Evidence Rose, Officials Played Hardball; Internal Message: 'Dodge!'; Company says 'Out of Context.'" As described more fully above, the November 1, 2004 Wall Street Journal article detailed, among other things, how even though Defendant's CEO expressed that the APPROVe study findings tying VIOXX® to heart attacks and strokes were unexpected, internal Merck e-mails, marketing materials and interviews with outside scientists indicated that Merck "fought forcefully for years to keep safety concerns from destroying the drug's commercial prospects." The article made, among others, the following critical points:

> • E-mails by and between Company executives in the mid to late 1990s showed that Merck knew that Vioxx increased the risk of cardiac events, and sought to conceal such financially damaging information;
>
> • The VIGOR results, released in March 2000, showed that Vioxx patients, as compared with those taking Naproxen, suffered five times as many heart attacks. In March 2000, defendant Scolnick e-mailed colleagues that the risk of cardiovascular events associated with Vioxx

were "clearly there," and was a "mechanism-based problem," but in a news release Merck offered no hint that anyone at the Company knew that Vioxx itself increased the risk of cardiovascular events. When it published the VIGOR results, Merck stated that the study's findings were consistent with the cardioprotective qualities of Naproxen--rather than the increased cardiovascular risks associated with Vioxx;

• When the VIGOR study results were published in the New England Journal of Medicine, it stated that among patients studied who were not already at high risk for heart attacks, Vioxx did not show a significant rise in heart attacks;

• A Merck training document entitled "Dodge Ball Vioxx" instructed sales representatives to dodge questions or concerns about the cardiovascular effects associated with Vioxx; and

• Merck attempted to suppress discussion about the VIGOR study results by, among other things, telephoning academics to complain about lectures the Company deemed to be "irresponsibly anti-Merck and specifically anti-Vioxx;" withdrawing financing from seminars at which doctors and academics who were critical of Merck's handling of Vioxx were scheduled to speak, and even filing suit to "correct" publications raising concerns about Vioxx's cardiovascular risks and criticizing Merck's handling of those concerns.

80. Each of the Defendant's statements made in 2004 concerning VIOXX® was materially false and misleading when made, because each statement failed to disclose the extent of the Company's knowledge that VIOXX® was in fact associated with a significant risk of cardiac events. The true but concealed and/or misrepresented facts included, but were not limited to:

• The Merck Defendants' removal of Dr. Cannuscio's name from the Harvard-Brigham Women's Study was a deliberate attempt by the Merck Defendants to conceal Vioxx's known risks;

• The Kaiser Permanente study confirmed the results of Study 090 and VIGOR, and thus demonstrated that Vioxx caused severe cardiovascular complications;

• Adequate justification for withdrawing Vioxx from the worldwide markets existed well before September 30, 2004, and the Merck

Defendants' attempts to base the withdrawal upon the putative results of the APPROVe study were knowingly false when made;

• The Company was aware that Vioxx itself created an increased risk of heart attack, and that its explanation for the VIGOR study results--that the Vioxx patients suffered greater incidences of cardiovascular events because of cardioprotective qualities of Naproxen--was inaccurate;

• The Company's statements refuting the results of the Brigham & Women's Hospital Study finding an increased risk of heart attack in patients taking Vioxx were unfounded;

• Merck's statements that the lawsuits filed against the Company with respect to Vioxx were meritless were, in fact, unfounded;

• The Company's announcements and press releases throughout 2004, stating that Merck 'stands behind the safety of Vioxx' were unfounded, because Merck knew that Vioxx, in fact, was associated with cardiovascular events and was therefore not safe;

• Merck's press releases "reconfirming the favorable cardiovascular safety profile of Vioxx" during 2004 were unfounded, because the Merck Defendants knew that Vioxx was associated with high cardiovascular risks;

• The Vioxx promotional activities that the FDA condemned in the September 17, 2001 FDA Letter stemmed from Merck Defendants' deliberate efforts to conceal Vioxx's known risks, which continued in 2004;

• Merck's unpublished Study 090 concluded that Vioxx users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

• Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved Vioxx for prescription use, Merck knew of the Vioxx-related medical risks;

• Substantial data existed in 1999 that Vioxx was associated with a higher risk of cardiovascular events than other NSAIDs;

• On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing defendants for misleading the public by using deceptive promotional materials that suggested Vioxx had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

• Defendant knew that the negative cardiovascular events were not due to the cardioprotective properties of Naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendants observed in Study 090; and

• Vioxx's safety profile was not "excellent" as the Defendant claimed, but was instead marked by an unacceptably high risk of negative cardiovascular events.

COUNT I
FRAUD

81. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

82. Defendant committed fraud against the State of Mississippi and all State agencies and instrumentalities that approved VIOXX® for reimbursement in reliance on the false and misleading safety and efficacy data provided, communicated and/or published by Defendant. Defendant knew that the safety and efficacy data it provided, communicated and/or published were false. Defendant provided such false data with the intent of inducing Mississippi agencies and instrumentalities to rely on the false information in determining pharmacy benefits related to VIOXX®.

83. Mississippi agencies and instrumentalities reasonably relied on such false information in approving VIOXX® for reimbursement. Defendant's fraudulent conduct is continuing, as it regularly and periodically continued to issue false data for publication concerning the safety and efficacy of VIOXX®.

84. As a result of Defendant's fraudulent conduct, the State of Mississippi, its agencies and instrumentalities, as well as the citizens of Mississippi, have been damaged by paying excessive amounts for Defendant's drug, VIOXX®, when it was no more effective than other less expensive NSAIDS, and when it exposed those who ingested the drug to substantial

adverse health effects, including the risks of heart attack and stroke. Defendant's conduct was knowing, intentional, with malice, demonstrated a complete lack of care, and was in conscious disregard for the rights of Plaintiff. Plaintiff is therefore entitled to an award of punitive damages.

COUNT II
VIOLATION OF MISSISSIPPI'S CONSUMER PROTECTION ACT

85. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

86. Defendant's representations as set forth herein, concerning the characteristics and benefits of VIOXX®, including its safety and efficacy, were false, misleading and untrue when made, and constitute a violation of Mississippi's Consumer Protection Act, § 75-24-1, *et seq.*, Miss. Code Ann.(1972)

87. Attorney General Jim Hood brings this action for a declaratory judgment that the Defendant's conduct as set forth herein, violated §75-24-1, *et seq.*, Miss. Code Ann.(1972) and seeks, pursuant to §75-24-9, an injunction to restrain the foregoing continuation of dissemination of false safety and efficacy information concerning VIOXX® to the public. Further, Plaintiff is entitled to civil penalties against Defendant, pursuant to § 75-24-19.

COUNT III
UNTRUE, DECEPTIVE, AND MISLEADING ADVERTISING
IN VIOLATION OF § 97-23-3 MISS. CODE ANN. (1972)

88. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

89. As stated herein, Defendant made false, deceptive and untrue statements and representations concerning the safety, risks, and effectiveness of VIOXX®, to the public generally, and Mississippians, specifically. These statements and representations were

published, circulated, disseminated, and placed before the public generally, and Mississippians, specifically, in print and media advertisements, in publications, and by other means. Such statements and representations were made with the intent to sell or distribute VIOXX® to Mississippians, directly or indirectly, and were made with the intent to increase the consumption of or demand for VIOXX® by Mississippians. Defendant knew when the statements and representations were made that the information concerning VIOXX® was untrue, deceptive or misleading.

90. The foregoing conduct of Defendant as alleged above constitutes unfair, deceptive and misleading advertising of VIOXX® in violation of § 97-23-3 Miss. Code Ann.(1972). As a result of Defendant's conduct, the State of Mississippi, its agencies and instrumentalities, as well as the citizens of Mississippi, have been damaged by paying excessive amounts for VIOXX®, when it was no more effective than other less expensive NSAIDS, and when it exposed those who ingested the drug to substantial adverse health effects, including the risks of heart attack and stroke.

COUNT IV
MEDICAID FRAUD

91. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

92. Defendant knowingly made, or caused to be made, false or misleading statements or representations in order to obtain payments for its pharmaceutical drug, VIOXX®, under Mississippi's Medicaid program. Such conduct constitutes Medicaid fraud in violation of § 43-13-223, *et seq.*, Miss. Code Ann.(1972).

93. As a result of the hereinabove described fraud upon the Plaintiff, Defendant is liable to Plaintiff in an amount equal to the full amount it received as a result of payments made

by Mississippi Medicaid for its drug, VIOXX®, plus an additional civil penalty equal to triple the full amount received by Defendant on account of these payments.

COUNT V
RESTITUTION/ UNJUST ENRICHMENT

94. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

95. As a result of the false and misleading statements and representations of the Defendant concerning its drug, VIOXX®, the State of Mississippi, its agencies and instrumentalities, and Mississippi citizens, paid excessive amounts in connection with purchases and/or reimbursements of purchases of Defendant's prescription drugs.

96. As a result of the excessive payments for VIOXX®, Defendant obtained increased sales and market share for its product, and, therefore, increased profits, and was unjustly enriched at the expense of the State of Mississippi, its agencies and instrumentalities and Mississippi citizens.

97. In equity and fairness, it is the Defendant, not the taxpayers of Mississippi, who should bear the costs of VIOXX®-related diseases. By avoiding its own duties to stand financially responsible for the harm done by its prescription drug, the Defendant has wrongfully forced the State of Mississippi to perform such duties and to pay the health care costs of VIOXX®-related diseases. As a result, the Defendant has been unjustly enriched to the extent that Mississippi's taxpayers have had to pay these costs.

98. By this Complaint, the Attorney General seeks damages in an amount which is sufficient to provide restitution and reimbursement to the State for the sums the State has expended as a result of the Defendant's wrongful conduct, with said amount to be determined at

trial and for damages in restitution for the sums of money to be paid by the State in the future on account of the Defendant's wrongful conduct.

COUNT VI
NEGLIGENCE

99. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

100. Defendant had a duty to exercise reasonable care in the marketing, advertising, sale and distribution of Defendant's pharmaceutical drugs, including VIOXX®.

101. Defendant breached that duty by the conduct alleged herein.

102. As a result of Defendant's breach, VIOXX® was marketed, advertised, sold, and distributed in the State of Mississippi, and the State of Mississippi, its agencies and instrumentalities and the citizens of Mississippi have been damaged by paying excessive amounts for VIOXX®, when it was no more effective than other less expensive NSAIDS, and when it exposed those who ingested the drug to substantial adverse health effects, including the risks of heart attack and stroke.

103. In addition, beneficiaries of the State's prescription drug programs sustained and/or will sustain adverse health effects as a result of the ingestion of VIOXX®, which was the intended and foreseeable use of Defendant's drug. Plaintiff was required and/or will be required in the future to provide medical assistance to these Medicaid recipients.

104. In breaching its duties to the Plaintiff, as described above, Defendant acted negligently and/or in reckless disregard for the truth, in that Defendant knew or should have known through information available exclusively to them and otherwise that VIOXX® did not have the safety and efficacy it promoted, and that if used in the manner intended by Defendant, those who ingested the drug were at an increased risk for severe adverse health effects, including

heart attacks and strokes. Defendant further knew or should have known that its aforesaid breach of duty would be substantially certain to result in the injuries complained of herein.

COUNT VII
INDEMNITY

105. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

106. As a direct and proximate result of the breaches of duty and omissions Defendants as alleged above, Plaintiff was obligated to pay, has paid, and will be required to pay millions of dollars for VIOXX®, and for the provision of necessary medical care, facilities and services for certain of those aforementioned Mississippi citizens injured by Defendant's drug, and unable to afford and otherwise obtain such necessary medical care, facilities and services.

107. Plaintiff was legally obligated to pay the aforementioned sums and did not conduct itself in any wrongful manner in being so obligated to pay and in paying the aforementioned sums. As stated hereinabove, Defendant has been unjustly enriched as a result of said payments.

108. In all fairness and justice, Defendant should indemnify Plaintiff for the provision of necessary medical care, facilities and services for those aforementioned Mississippi citizens injured by VIOXX®.

COUNT VIII
VIOLATION OF MISSISSIPPI'S PRODUCTS LIABILITY ACT

109. Defendant Merck, at all times relevant hereto, manufactured, tested, designed, marketed, promoted, distributed, sold and/or prescribed VIOXX® for use and consumption by consumers. At the time Defendant manufactured, promoted, tested, designed, packaged, promoted, marketed, distributed, sold and/or prescribed VIOXX®, in violation of Mississippi's

Product Liability Act, Miss. Code Ann. § 11-1-63, VIOXX® was designed in a defective manner and was unreasonably dangerous to plaintiffs and other users or consumers because, among other things, VIOXX® was likely to cause harm to users when consumed for its intended use and Merck failed to adequately warn of the potential side effects.

110. The VIOXX® consumed by consumers was not materially altered from the time of its manufacture and distribution up until the time of consumption.

111. VIOXX®, at the time of its manufacture, distribution, and sale and at all times material hereto, was defective and unreasonably dangerous to consumers for at least the following reasons:

a. Defendant's VIOXX® was not sold with an appropriate warning regarding the serious increased risk of injury, including, but not limited to, strokes, heart attacks, and cardiovascular disease.

b. The VIOXX® manufactured, tested, designed, marketed, promoted, distributed, sold and/or prescribed by Defendant was not safe as manufactured, designed, marketed, distributed, sold and prescribed;

c. Defendant failed to adequately test the safety of VIOXX® which would have shown that the substantial risk of serious injury and/or illness including, but not limited to, strokes, heart attacks, and cardiovascular disease;

d. Defendant knew or should have known that permanent damage, including harmful and permanent effects could result from the intended use of the drugs, but Defendant sold them anyway; and

e. Defendant knew or should have known that is was unreasonable to place VIOXX® in commerce and into the hands of consumers.

112. The VIOXX® manufactured, tested, designed, packaged, marketed, promoted, distributed, sold and/or prescribed by Defendant was never reasonably fit for the purposes for which it was sold, and the risk and dangers associated with its use outweighed the utility it provided.

113. Defendant Merck, through its sale and promotion of the drug VIOXX® to agencies and instrumentalities of the State of Mississippi, breached its warranty of fitness for the purpose of proper medicinal uses free of out-of-balance side effects, and failed to conform to its own factual representations that the use of the product was safe. These actions, related to the defective conditions, rendered the product unreasonably dangerous to the consumers of the State of Mississippi, and caused additional expense related to their use by the State.

114. As a direct and proximate result of Defendant's unlawful and illegal conduct, the State of Mississippi has been, and continues to be, damaged.

COUNT IX
INJUNCTIVE RELIEF

115. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

116. The Defendant has engaged in many years of promoting and distributing for sale the prescription drug VIOXX®, under the guise of its safety and efficacy, despite its knowledge that the drug could and did cause physical harm to persons taking the drug as prescribed. Such conduct is a violation of the laws of the State of Mississippi, and has created a health care burden for the State totaling millions of dollars.

117. It is necessary and essential to stop the Defendant from promoting the sale of VIOXX®, a remedy which can only be effectively accomplished by enjoining the Defendant

from not only promoting the sale of Vioxx, but additionally in engaging in the sale or distribution of Vioxx.

118. If such injunction enjoining the Defendants from promoting the sale of its prescription drug VIOXX® is not granted, the citizens of the State of Mississippi who thereafter ingest the drug will be irreparably harmed in that they will be substantially certain to suffer adverse health consequences.

119. It is in the public interest to enjoin the Defendant from promoting the sale of VIOXX®.

120. By this Complaint, the Attorney General seeks an injunction to be issued against the Defendant to prohibit it from promoting the sale of VIOXX®, and from engaging in the sale and distribution of said prescription drug.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for relief as follows:

(1) an Order enjoining the Defendant from promoting the sale of VIOXX®, and from engaging in the sale and distribution of VIOXX®;

(2) an Order declaring that the Defendant's conduct violated Miss. Code Ann. § 75-24-1, *et* seq, (1972) and Miss. Code Ann. § 11-1-63 and an injunction to restrain Defendant from engaging in practices in violation of Miss. Code Ann. §75-24-9 (1972), including the continuation of dissemination of false safety and efficiency information condoning VIOXX® to the public;

(3) an award of civil penalties against Defendant, pursuant to Miss. Code Ann. § 75-24-19(1972);

(4) an award pursuant to Miss. Code Ann. § 43-13-223, *et seq.*, (1972), of an amount equal to the full amount Defendant received as a result of payments made by the Mississippi Department of Medicaid for VIOXX®, plus an additional civil penalty equal to triple the full amount received by Defendant on account of these payments;

(5) an award of compensatory damages to Plaintiff in such amount as is proved at trial;

(6) an award of punitive damages;

(7) an award of attorney's fees and prejudgment interest at the legal rate of interest, and such other equitable, declaratory and further relief as the Court may deem appropriate.

JIM HOOD, ATTORNEY GENERAL,
***ex rel.*, STATE OF MISSISSIPPI**

BY: _____

Rickey T. Moore (M.S.B. #3457)
Geoffrey C. Morgan (M.S.B. #3474)
Office of the Attorney General
Post Office Box 220
Jackson, MS 39205
Telephone: (601) 359-3821

OF COUNSEL:

Sheila M. Bossier (M.S.B. #10618)
John T. Kitchens (M.S.B. #4188)
BOSSIER & KITCHENS, PLLC
1520 N. State Street
P. O. Box 55567
Jackson, MS 39296
Telephone: (601) 352-5450
Facsimile: (601) 352-5452

W. Mark Lanier (*pro hac vice* application pending)
Richard Meadow (*pro hac vice* application pending)
Lawrence P. Wilson (*pro hac vice* application pending)
The Lanier Law Firm
6810 FM 1960 West
Houston, Texas 77069
Telephone: (713) 659-5200
Fax: (713) 659-2204

James E. Fosler
Fosler Law Group, Inc.
737 West Fifth Ave., Suite 205
Anchorage, Alaska 99501
Telephone: (907) 277-1557
Fax: (907) 277-1657

Attorneys for Plaintiff

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. MERCK & CO., INC., Defendant.	Case No: 3AN-05- 14 292 Ci

COMPLAINT

(AS 45.50.471, AS 45.50.501, AS 45.50.551)

The State of Alaska, Plaintiff herein, by and through its counsel, brings this Complaint against Merck & Co., Inc. ("Defendant") pursuant to the Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 *et seq.*

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DEFENDANT

1. Defendant is an American pharmaceutical company incorporated under the laws and statutes of the State of New Jersey. Defendant can be served with process by serving its registered agent, CT Corporation System, 801 W. 10th Street, Suite 300, Juneau, Alaska 99801.

JURISDICTION AND VENUE

2. At all times material to this civil action, Defendant transacted business in Alaska by, among other things, advertising, soliciting, selling, and distributing the pharmaceutical product known as Vioxx to purchasers in Alaska. Therefore, this court has personal jurisdiction over Defendant.

3. This court has subject-matter jurisdiction based upon AS 45.50.501 and 45.50.551, which provide remedies to redress Defendant's conduct and authorize the State of Alaska to bring this action.

4. Because the State of Alaska is not a citizen for purposes of diversity jurisdiction, no federal court can exercise subject-matter jurisdiction over this case by virtue of diversity of citizenship. *State of Alaska v. K&L Distributors, Inc.*, 318 F.2d 498, 498 (9th Cir. 1963); *Tex. Dept. of Hous. & Cmty. Affairs v. Verex Assurance, Inc.*, 68 F.3d 922, 926 (5th Cir. 1995).

5. Venue is proper in this judicial district pursuant to Section 45.50.501 of the Alaska Statutes and Rule 3 of the Alaska Rules of Civil Procedure because some of

Defendant's unlawful acts and practices that give rise to this Complaint arose in this judicial district and the Defendant is doing business in this judicial district.

DEFENDANT'S CONDUCT

6. All practices, acts, and omissions alleged herein to have been committed by Defendant were committed by Defendant's officers, directors, employees, or agents, who, at all times, acted on behalf of Defendant and whose practices, acts, and omissions were authorized and/or ratified by Defendant. Accordingly, Defendant is liable under the doctrines of vice-principal, respondeat superior and agency as those terms are defined and applied under the laws and statutes of Alaska.

7. Defendant began marketing Vioxx (generic name Rofecoxib) in May 1999, following a short clinical trial period. Vioxx was initially approved for osteoarthritis, the management of acute pain in adults, and the treatment of primary dysmenorrhea. Furthermore, in requesting that Vioxx be placed on the Alaska Medicaid Program's list of drugs subject to reimbursement, the Defendant represented that Vioxx was at least as safe as other drugs of a similar class and/or type used for the same purposes. Ultimately, Defendant withdrew Vioxx from the market on September 30, 2004, because it was unsafe. Research and clinical experience has revealed that Vioxx significantly increases the risk of heart attack and other serious cardiovascular and cerebrovascular medical complications.

8. From the time Defendant started developing Vioxx, through the date of its withdrawal from the market on September 30, 2004, Defendant engaged in knowing

misrepresentations, including, but not limited to, direct representations to the Alaska Medicaid Program that Vioxx was safe and effective and advertising and promotional campaigns to Alaskans that falsely represented the safety of Vioxx. The Defendant misrepresented and suppressed evidence concerning the significant health hazards of Vioxx.

9. Defendant was aware that Vioxx caused serious and significant health hazards even before Defendant promoted Vioxx to physicians and to the State of Alaska and provided Vioxx to Alaskans. Defendant knew that cerebrovascular and cardiovascular problems occurred more frequently in patients receiving Vioxx than in patients receiving placebos or other medicines. Defendant's internal memos and e-mails, dating back to at least 1996, show that Defendant knew "how" and "why" Vioxx would cause significantly higher rates of cardiovascular problems in patients taking Vioxx, as compared to a control group.

10. Before Defendant began marketing Vioxx to the public in May 1999, Defendant knew clinical research, including its own, showed that Vioxx increased the risk of heart attack and adverse cardiovascular and cerebrovascular problems. However, Defendant did not disclose this prior knowledge, nor the additional knowledge Defendant obtained after it started successfully selling Vioxx to the public. Instead, the Defendant misrepresented and mischaracterized the data and information concerning Vioxx. Moreover, the Defendant launched an expensive, promotional advertising campaign to convince lay people to request Vioxx from their healthcare professionals for the treatment of their pain, and to promote, as safe, the use of Vioxx, even though the Defendant's own medical research confirmed its harmful effects. The Defendant also launched an aggressive campaign of intimidation against

researchers and physicians who questioned the safety of Vioxx. The Defendant's deceptive and misleading representations were later recognized by the FDA in a letter to the Defendant wherein the FDA labeled the Defendant's promotional sales marketing and materials as "lacking in pure balance," "false," and "misleading." In recent months, investigators have learned that the Defendant deliberately removed data of some adverse cardiovascular and cerebrovascular events from data supplied to those outside the company.

11. It was not until September 30, 2004, that the Defendant finally admitted that Vioxx was not safe and posed such an unreasonable risk of harm to the public that it should be withdrawn from the market.

VIOLATIONS OF THE UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACT

12. Defendant's acts and practices were unlawful as that term is described in AS 45.50.471(a) in that Defendant used unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce.

13. Defendant represented to the State, to physicians in Alaska, and to the public in Alaska that Vioxx had characteristics, uses, and benefits that it did not have. AS 45.50.471(b)(4).

14. Defendant advertised Vioxx with an intent not to sell it as advertised. AS 45.50.471(b)(8).

15. Defendant engaged in conduct creating a likelihood of confusion or of misunderstanding and which misled, deceived, or damaged buyers of Vioxx, including the

State of Alaska, healthcare providers in Alaska, and Alaskans in general. AS 45.50.471(b)(11).

16. Defendant used and employed deception, fraud, and misrepresentation to further the sales of Vioxx. Defendant knowingly concealed, suppressed, and omitted one or more material facts with the intent that others rely on the concealment, suppression, and omission in connection with the sale and advertisement of Vioxx. AS 45.50.471(b)(12).

17. Defendant knowingly or intentionally concealed or failed to disclose evidence that revealed the truth concerning the significant increased risk of heart attack and other cardiovascular problems caused by Vioxx. In addition, Defendant knowingly or intentionally set out on a course of concealing this evidence by misrepresenting the data in published literature and in advertising campaigns, and by threatening and attempting to coerce those who chose to criticize Defendant, to warn the public and the health care community, and to tell the truth about the significant risks posed by Vioxx. This conduct violates the Unfair Trade Practices and Consumer Protection Act.

18. Defendant knowingly or intentionally made, caused to be made, induced, or sought to induce the making of false statements or misrepresentations of material fact concerning the safety, or lack thereof, of Vioxx, which is information required to be provided by state law, rule, regulation, and/or provider agreement to the Alaska Medicaid Program. This conduct violates the Unfair Trade Practices and Consumer Protection Act.

19. Defendant knowingly and intentionally made claims under the Alaska Medicaid Program for a product that is substantially inadequate or inappropriate when compared to

generally recognized standards within the health care industry or for a product that is otherwise inappropriate. This conduct violates the Unfair Trade Practices and Consumer Protection Act.

20. Defendant's knowing or intentional acts and omissions constitute repeated violations of the Alaskan statutory laws. Defendant has now admitted that Vioxx is unsafe and has taken it off the market.

CAUSATION OF DAMAGES

21. Defendant's unlawful acts and practices induced a great many Alaskans to purchase Vioxx.

22. Defendant's unlawful acts and practices induced the State of Alaska to authorize expenditure of Medicaid funds for the purchase of Vioxx.

23. Defendant's unlawful acts and practices resulted in the expenditure of millions of dollars of state funds or state controlled funds on Vioxx.

24. Defendant's unlawful acts and practices were a cause-in-fact, producing cause, and proximate cause of the purchase and expenditures described in paragraphs 21 thru 23 and have necessitated this action.

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PRAYER FOR RELIEF

WHEREFORE, the State of Alaska demands judgment as follows:

1. For money damages in an amount that far exceeds the $100,000 minimum jurisdictional limit of this court;

2. For restitution damages for the value of all payments that the State of Alaska made for Vioxx prescriptions;

3. For treble damages;

4. For civil penalties of $5,000 for each separate violation of the Unfair Trade Practices and Consumer Protection Act;

5. For punitive damages;

6. For costs and attorneys' fees;

7. For prejudgment interest;

8. For post judgment interest;

9. For all other relief deemed just and equitable by the Court.

DATED: December 23, 2005.

Respectfully submitted,

FOSLER LAW GROUP, INC.

JAMES E. FOSLER
Alaska Bar No.: 9711055

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William A. Rossbach
ROSSBACH HART BECHTOLD, PC
401 North Washington Street
Missoula, MT 59802
Telephone (406) 543-5156
Fax No. (406) 728-8998

E. Craig Daue, Esq.
BUXBAUM, DAUE & FITZPATRICK, PLLC
228 West Main, Suite A
P.O. Box 8209
Missoula, MT 59807
Telephone: (406) 327-8677
Fax No.: (406) 829-9840

Attorneys for Plaintiff

MONTANA FIRST JUDICIAL DISTRICT COURT,

LEWIS & CLARK COUNTY

THE STATE OF MONTANA,
ex rel MIKE McGRATH,
Attorney General,

Plaintiff,

-vs-

MERCK & CO., INC.,

Defendant.

Cause No. ADV-2005-819

COMPLAINT

The State of Montana, by and through the Attorney General of Montana, Mike McGrath, asserts the following claims against Merck & Co., Inc. (Merck)

I. NATURE OF THE CLAIM

This is a civil action for damages and civil penalties for violations of the Montana Food Drug and Cosmetic Act, the Montana Consumer Protection Act, and the other causes of action stated herein. The action is brought by the Montana Attorney General in the exercise of his common law and statutory powers. At all times relevant, Defendant Merck knew and had reason to know that its drug. Vioxx. was not safe for its intended purpose; that

Vioxx put users at risk for cardiovascular injuries and could cause potentially fatal myocardial infarctions, both obvious and silent, as well as other adverse cardiovascular events, including ischemic strokes and death. Merck also knew that Vioxx was no more effective than other traditional, and much less expensive, non-steriodal anti-inflammatory drugs commonly available for treatment of acute and chronic pain and knew that, except in a very few patients with severe gastrointestinal problems, the use of Vioxx was neither medically nor financially justified. Despite this knowledge, Merck misrepresented the safety of Vioxx and manufactured, advertised, promoted, marketed, and sold Vioxx as a safe prescription medication when it knew that was not true. Moreover, Merck misrepresented the effectiveness of Vioxx in comparison to other non-steriodal anti-inflammatory drugs and misrepresented and over-promoted its use when it was not medically justified. As a consequence of Merck's false advertising, promotion, and marketing of Vioxx and other misrepresentations, the State of Montana and its private citizens and corporate entities were injured and damaged and caused to spend money on Vioxx that was not medically justified and that actually caused cardiovascular injuries, disability, and death.

II. DEFENDANT'S CONDUCT

1. The human body naturally produces two forms of cyclo-oxygenase enzymes (COX-1 and COX-2) that contribute to and are associated with inflammation and pain. Non-steriodal anti-inflammatory drugs (NSAIDs) have the potential to relieve pain and inflammation by inhibiting the production of these enzymes. Many NSAIDs have been developed for human use since aspirin was first formulated in 1897. Traditional NSAIDs like aspirin, ibuprofen, and naproxen reduce pain and inflammation by inhibiting production of both COX-1 and COX-2 enzymes.

2. Merck developed Vioxx during the 1990s. Vioxx is in the class of NSAIDs known as COX-2 inhibitors. COX-2 drugs inhibit the production of the COX-2, but not the COX-1 enzyme. COX-2 inhibitors tend to create less irritation to the stomach and intestines than the earlier NSAIDs that inhibit both COX-1 and COX-2. However, although they reduce gastrointestinal irritation, Vioxx and other COX-2 drugs also increase

cardiovascular risk. As shown below, Merck has known this since early in its development of Vioxx. Nevertheless, because of the competition with other companies for market share for treatment of acute and chronic pain and particularly arthritis, Merck wanted to get Vioxx onto the market as quickly as possible.

3. Dr. Alan S. Nies, a Merck scientist who led the Vioxx development program in the 1990's, developed a plan in 1996 to expedite federal approval of Vioxx because of fear that Celebrex, a competing drug by Pfizer, would get approval first. Dr. Nies' 1996 plan identified the Celebrex market goal of late 1998 and set the same goal for Vioxx. The document also noted an "accelerated and compressed" drug development strategy by beginning some clinical studies before others were finished.

Before Obtaining FDA Approval, Merck Knew That Vioxx Increased the Risk of Heart Attacks.

4. Even while it was working to expedite approval of Vioxx, Merck knew very early that Vioxx lacked the beneficial anti-platelet effects of aspirin and aspirin-like NSAIDs. At the site of an injury, blood platelets clump together to help form a clot and prevent the loss of blood. When blood clots form inside arteries supplying blood to the heart or brain, heart attacks and strokes can occur. Aspirin and certain other NSAIDs reduce platelet aggregation and the formation of clots, thereby reducing the risk of heart attack and stroke in many patients.

5. In 1996, a Merck employee discussing a proposed trial to compare Vioxx to other NSAIDs stated that if patients receiving Vioxx in the trial were not allowed to take aspirin, "there is a substantial chance that significantly higher rates" of cardiovascular problems would occur in the patients taking Vioxx.

6. Merck official, Briggs Morrison, stated in a February 25, 1997, e-mail that unless patients taking Vioxx in the trial also took aspirin, "you will get more thrombotic events and kill [the] drug."

7. In a 1997 e-mail addressing the subject of whether patients taking Vioxx in the trial should also take aspirin, Merck scientist, Alise Reicin, stated that "the possibility of

increased CV [cardiovascular] events is of great concern." Ms. Reicin suggested that patients with a high risk of cardiovascular problems be excluded from the trial so that the increased rate of cardiovascular problems in the group taking Vioxx "would not be evident."

8. By April 1998, Merck scientists had also learned that COX-2 inhibitors, such as Vioxx , reduce the production of prostacyclin, a naturally occurring compound in the body that prevents blood platelets from clumping together. Merck, therefore, knew that Vioxx not only lacks the beneficial anti-platelet effect of aspirin and certain other NSAIDs, it also disables one of the blood vessels' main defenses against the clumping of platelets.

9. In 1998, Merck sought patent protection for a way to reduce cardiovascular problems in COX-2 inhibitors such as Vioxx. Merck obtained a patent for such a drug, or combination of drugs, in September 1999 from the World Intellectual Property Organization.

10. Before Vioxx was approved for sale in the United States, Merck knew that it contributed to the aggregation of blood platelets, putting users at risk for adverse cardiovascular effects, and knew that it could cause potentially fatal myocardial infarctions, both obvious and silent, and cerebrovascular events such as ischemic strokes and death.

11. Merck received approval from the Federal Food and Drug Administration (FDA) in May 1999 to sell Vioxx in the United States for the treatment of osteoarthritis and acute pain in adults.

After Obtaining FDA Approval, Merck Knew of Additional Evidence That Vioxx Increases the Risk of Heart Attacks

12. In 1999, Merck initiated a study of Vioxx titled "Vioxx Gastrointestinal Outcomes Research," or VIGOR. In March 2000, the results of VIGOR showed that patients in the study taking Vioxx suffered heart attacks at a rate 4 times higher than patients taking the older NSAID naproxen. Later analysis of the VIGOR data revealed that the rate was actually 5 times higher.

13. On March 9, 2000, Dr. Edward Scolnick, a senior Merck research official, sent an e-mail acknowledging that cardiovascular events caused by Vioxx "are clearly there," and that the cardiovascular effect "is mechanism based as we worried it was."

14. In 2000, Merck officials issued a "Confidential Memorandum of Invention." In that document, they stated that because Vioxx might cause cardiovascular problems, Merck should consider applying for a patent on combining Vioxx with another drug that would protect against cardiovascular problems from blood clots.

15. In March 2001, Merck filed a patent application for a drug combining Vioxx with a thrombaxane synthase inhibitor to help protect against the clotting problems caused by Vioxx. The application lists Dr. Edward Scolnick as the primary inventor.

16. Although Merck sought patent protection for ways to lessen the cardiovascular risks of Vioxx, it never produced such drugs. Instead, Merck continued to manufacture and market Vioxx as a stand alone drug.

17. In June of 2000, pharmaceutical industry-sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck was a member and a corporate sponsor, showed that Vioxx use resulted in statistically significant increases in hypertension and myocardial infarction.

18. In the journal *Pharmacy Today*, Merck publicly denied the validity of the results of the studies presented at the June 2000 EULAR study, especially with respect to the hypertension problems identified in that study.

Merck Publicly, and By Direct Communication to Prescribing Doctors, Made False and Misleading Statements about the Safety and Efficacy of Vioxx

19. The results of the VIGOR trial were announced to the public on March 27, 2000, and were published in the *New England Journal of Medicine* on November 23, 2000. The VIGOR trial showed that patients receiving Vioxx were 5 times more likely to suffer a heart attack than those who received the older NSAID naproxen.

20. To counteract this adverse information, Merck improperly pooled internal unpublished data to produce a misleading promotional device, titled the "Cardiovascular Card," which misrepresented the true risk of adverse cardiovascular events of Vioxx compared to traditional NSAIDs. On April 28, 2000, Merck issued a bulletin instructing its salespeople to use this Cardiovascular Card (CV Card) if doctors asked them about

cardiovascular risks of Vioxx. Instead of telling doctors the truth Merck knew about the cardiovascular risk shown in the VIGOR study, the bulletin required salespeople to point doctors to charts which listed "Overall Mortality Rates" purporting to show that patients on Vioxx were 11 times less likely to die than patients on other NSAIDs and were 8 times less likely to die of heart attacks and strokes. Merck told its salespeople to use the CV Card to "[e]nsure that the physician agrees that the cardiovascular events seen with Vioxx in OA clinical trials were low and similar to [other NSAIDs]."

21. The April sales bulletin instructed salespeople never to raise the subject of cardiovascular risks of Vioxx when talking to doctors. Merck treated questions by doctors about the cardiovascular risks of Vioxx as "obstacles." The April 28, 2000, Merck bulletin states: "The Cardiovascular Card is an obstacle handling piece and should only be used with physicians in response to their questions regarding the cardiovascular effects of Vioxx." Merck told its salespeople never to leave a CV Card with a doctor or allow a doctor to make a copy of the card.

22. On February 8, 2001, the FDA conducted an Arthritis Advisory Committee meeting at which questions about the safety of Vioxx were extensively reviewed. At the meeting, Merck presented a large, pooled analysis of all Vioxx trials. In response, FDA officials told the advisory committee that pooling data from different studies to assess safety, as Merck was doing, was fundamentally flawed.

23. The FDA Arthritis Advisory Committee concluded that doctors should be told that the VIGOR study showed "an excess of cardiovascular events in comparison to naproxen."

24. The next day, contrary to the FDA Arthritis Advisory Committee recommendation, Merck sent another emergency bulletin to its salespeople stating: "DO NOT INITIATE DISCUSSIONS ON THE FDA ARTHRITIS ADVISORY COMMITTEE . . .OR THE RESULTS OF THE . . . VIGOR STUDY." The bulletin further ordered salespeople to "[s]tay focused on the EFFICACY message for Vioxx."

25. The bulletin referred to its contents as "Updated Obstacle Responses," and closed by reminding salespeople: "Do not proactively discuss the Advisory Committee Meeting or VIGOR."

26. On May 22, 2001, the *New York Times* published an article raising questions about VIGOR and the cardiovascular safety of Vioxx. The very same day, Merck issued a press release responding to the *New York Times* article. The press release stated: "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx." The press release referred to the pooled data from pre-approval studies and claimed that: "there was no difference in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx, other NSAIDs and placebo."

27. A day later, in response to the unfavorable press, Merck sent another emergency bulletin to its field sales staff, once again instructing them to counter the *Times* article by displaying the CV Card and highlighting data on the card suggesting that Vioxx was safer than other NSAIDs. It advised its sales representatives to tell doctors that Merck's data showed that cardiovascular mortality was actually 8 times less than other NSAIDs.

28. In July 2001, an article in *WEB MD* quoted an FDA Study stating: "[T]he study found that Vioxx cut the occurrence of ulcers and other gastrointestinal problems by half compared with the over-the-counter NSAID Aleve. But the study showed that people taking Vioxx had four times the risk of a heart attack."

29. In response, Merck's spokeswoman, Christine Fanelle, replied that the "risk was negligible," and that "it appeared to increase the risk of a heart attack because Aleve, like aspirin, actually reduces heart attack risks."

30. On August 22, 2001, the *Journal of the American Medical Association* (JAMA) published an article authored by cardiologists Eric J. Topol, M.D., Debarata Mukherjee, M.D., and Steven E. Nessen, M.D. of the Cleveland Clinic Foundation entitled, "Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors." The JAMA article reported the Cleveland Clinic's evaluation of two randomized trials of more than 15,000 patients, comparing Pfizer's Celebrex in a study called CLASS and Merck's VIGOR Study

involving Vioxx. The Cleveland Clinic reported that: "[T]he annualized myocardial infarction rates for COX-2 inhibitors in both VIGOR and CLASS were significantly higher than that in the placebo group . . . ."

31. The day before the JAMA article was published, Merck issued a statement claiming: "We have additional data beyond what they cite, and the findings are very, very reassuring. Vioxx does not result in any increase in cardiovascular events compared to placebo."

32. On that same day, Merck executive, Jo Jerman, also delivered a voice mail to company field representatives reassuring them and instructing them again to use the CV Card if asked about cardiovascular effects, reminding them that the card showed that cardiovascular mortality rates were similar for Vioxx and other NSAIDs.

33. On August 23, 2001, the day after the JAMA article was published, Merck stated in another press release: "The Company stands behind the overall and cardiovascular safety profile . . . of Vioxx."

34. Each time there was any public concern raised about the safety of Vioxx, Merck responded by instructing its field staff to focus on using the misleading CV Card to overcome any hesitation or concerns by the prescribing doctors.

35. In a 2001 direct letter to doctors, Merck seriously understated the heart risks faced by patients taking Vioxx. Merck reported that, in patients taking Vioxx in the largest clinical trial of the drug ever, only 0.5 percent had incurred "cardiovascular events," or heart and circulation problems. In fact, 14.6 percent of the Vioxx patients had cardiovascular problems while taking the drug, according to Merck's own report on the study to federal regulators. In addition, 2.5 percent had serious problems, like heart attacks.

36. On September 17, 2001, the FDA issued a WARNING LETTER to Merck stating that: "[Y]our claim in the press release that Vioxx has a 'favorable cardiovascular safety profile,' is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDS is misleading . . . ." The WARNING LETTER also makes the following

statements about Merck's promotion of Vioxx.

> [T]he Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed your promotional activities and materials and has concluded that they are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act.
>
> . . . .
>
> You assert that Vioxx does not increase the risk of MIs and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties.
>
> . . . .
>
> Your minimizing these potential risks and misrepresenting the safety profile for Vioxx raise significant public health and safety concerns. Your misrepresentation of the safety profile for Vioxx is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for Vioxx that also misrepresented Vioxx's safety profile.
>
> . . . .
>
> The promotional audio conferences identified above, arranged by, and presented on behalf of, Merck were false or misleading in that they minimized the MI results of the VIGOR study, minimized the Vioxx/Coumadin drug interaction, omitted important risk information, made unsubstantiated superiority claims, and promoted Vioxx for unapproved uses and an unapproved dosing regimen.
>
> . . . .
>
> Your suggestion that COX-2 inhibitors, including Vioxx, have an overall safety profile that is superior to other NSAIDs is misleading because such an advantage has not been demonstrated. In fact, in the VIGOR study the incidence of serious adverse events was **higher** in the Vioxx treatment group than in the naproxen treatment group . . . .
>
> . . . .
>
> Your audio conferences are misleading because they promote Vioxx for unapproved uses . . . . Your claim is misleading because it suggests that Vioxx is effective for the treatment of rhemuatoid arthritis when this has not been demonstrated.
>
> . . . .
>
> Your promotional audio conferences are also misleading because they suggest that Vioxx is safe and effective for other unapproved uses such as the prevention of cancer and invasive cancer, and for the treatment of Alzheimer's disease and gout.

. . . .

> The promotional activities and materials described above minimize the potentially serious cardiovascular findings that were observed in the VIGOR study, minimize the Vioxx/Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses.

(COX-2 Notebook 2, Tab 58.)

37. Neither the adverse journal and newspaper articles nor the FDA criticisms did anything to hinder Merck's aggressive marketing of Vioxx. In the Fall of 2001, Merck launched Project Offense to increase Vioxx market share, focusing on efficacy to divert attention from the safety concerns. Project Offense included instructions to field sales staff on how to address physician safety concerns, advising them again to review the entire CV Card with doctors, and point out to them Merck's data which purported to show that Vioxx was actually safer than other NSAIDs.

Merck Resisted Changes Recommended by the FDA to Warn about Heart Attack Risks in Vioxx Labeling

38. After the VIGOR study, the FDA recommended that the label for Vioxx be changed to add a warning which included a statement that: "The risk of developing myocardial infarction in the VIGOR study was five fold higher in patients treated with Vioxx 50 mg (0.5%) as compared to patients treated with naproxen (0.1%) . . . ." Merck objected to the change recommended by the FDA.

39. On February 15, 2002, the FDA recommended that the Vioxx label include a Kaplan-Meier curve to graphically show a worsening of cardiovascular risks as the length of exposure to Vioxx increased. Merck again objected.

40. In addition to the misleading CV Card, Merck developed a number of other materials designed to misrepresent the safety and efficacy of Vioxx. It produced a videotape to train its salespeople to view doctors' concerns about Vioxx's heart risks as "'obstacles" to be avoided or dismissed.

41. Merck produced a training document titled "Dodge Ball Vioxx," consisting of 12 pages of statements or questions a salesperson might receive from a doctor about the

cardiovascular safety of Vioxx. The last 4 pages of the document contain the single word "DODGE!" in capital letters.

Merck Attempted to Suppress and Refute Research Showing That Vioxx Increases the Risk of Heart Attacks

42. Two months after Vioxx went on the market in 1999, Nancy Santanello, head of Merck's epidemiology department, wrote an e-mail about "physicians to neutralize:" Her email states: "Attached is the complete list of 36 physicians to neutralize with background information and recommended tactics. You will notice that some have already been 'neutralized'." That e-mail also identified a previous e-mail which had a subset of the 36 physicians "we would like to get involved in Merck clinical research" and that the e-mail's recipient should "be aware of our most challenging (and also most vocal) national and regional physicians."

43. During 1999, Merck paid Dr. Gurkipal Singh of Stanford University Medical School up to $2,500 for giving talks to other doctors supporting the use of Vioxx. Dr. Singh gave 40 talks over 7 months. Dr. Singh became concerned about the cardiovascular risks of Vioxx after the VIGOR study was completed. Dr. Singh repeatedly asked Merck for the VIGOR data so he could analyze them for himself. When Dr. Singh persisted in his requests, Merck warned him that there would be serious consequences if he didn't stop. In 2000, Dr. Singh began to publicly express his concern about the cardiovascular risks of Vioxx.

44. A dossier of Dr. Singh's activities regarding Vioxx was prepared for Merck senior vice president, Dr. Louis Sherwood. On October 28, 2000, Dr. Sherwood called Dr. Singh's boss, Stanford Medical School professor Dr. James Fries, and hinted that there would be repercussions for Stanford if Dr. Singh continued making public statements about the cardiovascular risks of Vioxx.

45. In January 2001, Dr. Fries wrote to former Merck CEO, Ray Gilmartin, complaining that Dr. Sherwood had called him to try to get him to make Dr. Singh stop saying negative things about Vioxx in lectures. Sherwood warned that if Dr. Singh didn't stop bashing Vioxx, he would "flame out" and "there would be consequences for [Dr.

Sherwood] and Stanford."

46. Merck sponsored a study of Vioxx by several doctors, including Dr. Daniel Solomon and Dr. Jerry Avorn. Merck scientists helped develop the study protocol and signed off on all aspects of the study design. However, when the study showed an increased risk of heart attacks with Vioxx, Merck required one of the study's coauthors, who was an employee of Merck, to remove her name from the study. Although it funded the study and approved its design, Merck publicly discredited the study in May 2003, claiming that there were "serious limitations to the analysis."

Merck Deleted Data About Heart Attacks From an Article in *The New England Journal of Medicine*, Causing the Article to be Incomplete and Deceptive

47. In November 2000, an article reporting on the VIGOR study, an important clinical trial of Vioxx, was published in *The New England Journal of Medicine*. *The New England Journal* is one of the world's most prestigious and influential medical journals. The VIGOR study was financed by Merck and produced information about heart attacks suffered by study participants who took Vioxx and by those who took naproxen instead of Vioxx. Throughout its marketing campaign for Vioxx, Merck relied on the VIGOR article in *The New England Journal* to support its claim that Vioxx was safe.

48. The VIGOR study showed that 20 of the participants taking Vioxx had heart attacks compared to only 4 of the participants taking naproxen. Although at least 2 of the 3 lead authors of the article that appeared in *The New England Journal* knew several months before the article was published that there were 20 heart attacks among the participants taking Vioxx, the article reported that 17, not 20, of the Vioxx participants had heart attacks.

49. Electronic records show that two days before the article was submitted to *The New England Journal* for publication, a Merck editor deleted information about 3 of the heart attacks in the Vioxx participants. The data deleted by Merck made Vioxx appear less risky in the article than the VIGOR trial actually proved that it was. Merck knew that, by deleting data about heart attacks, the article would present an incomplete, inaccurate, and deceptive picture of the true risk of taking Vioxx.

50. The editors of *The New England Journal* have publicly stated that the information deleted by Merck calls into question "the integrity of the data" appearing in the article, and have called for the article's authors to submit a correction.

Merck Pressured Doctors to Prescribe Vioxx, and Urged Patients to Ask For It, Even Though it Was Far More Dangerous and Expensive than Other Equally Effective Drugs

51. Studies by the Mayo Clinic, the Veterans Affairs Department, and the Kaiser Permanente organization showed that Vioxx is no more effective in relieving pain than other NSAIDs such as aspirin, ibuprofen, and naproxen which can be purchased without a prescription at a fraction of the cost of Vioxx.

52. Only a small percentage of people who took Vioxx were at high risk of stomach bleeding if they took NSAIDs that blocked COX-1 and COX-2. However, Merck promoted Vioxx to doctors and patients as a drug of first choice in treating pain. Thus, although the majority of people who took Vioxx did not need, or benefit from, Vioxx's reduced effect on the stomach, all people who took Vioxx were exposed to a five-fold increase in the risk of heart attacks.

53. All Vioxx sold in Montana cost many times more than generic aspirin, ibuprofen, and naproxen. Furthermore, a combination of a generic NSAID, such as ibuprofen or naproxen, with a drug that protects the stomach, such as Prilosec, is almost as safe for the stomach as Vioxx, with no increased heart attack risk.

Merck Aggressively Marketed Vioxx to the Public and to Doctors

54. Despite knowing before and after FDA approval that Vioxx caused increased cardiovascular risk, Merck has aggressively marketed Vioxx from the beginning.

55. When Merck launched its marketing campaign for Vioxx in 1999, it hired 700 new salespeople to market the drug to doctors and eventually assigned over 3,000 salespeople to promote Vioxx in face-to-face discussions with doctors.

56. Merck put its salespeople through intensive training exercises to persuade doctors to prescribe Vioxx and provided numerous incentives to Merck salespeople for increasing the share of Vioxx that any doctor prescribed.

57. Salespeople were instructed to use the systems and techniques it had taught them to convince doctors that Vioxx was a safe and effective pain reliever. On information and belief, it is alleged that Merck salespeople used some or all of the required sales tactics to induce Montana doctors to prescribe Vioxx to Montana citizens.

58. On October 3, 2001, Merck launched a direct-to-consumer advertising campaign for Vioxx with television ads featuring Olympic skater Dorothy Hamill. These ads ran repeatedly in Montana. The ads failed to warn consumers that Vioxx increased the risk of cardiovascular problems.

59. Merck's Vioxx advertising and marketing campaign as a whole sought to create the image, impression, and belief that Vioxx was safe for adults and had fewer side-effects and adverse reactions than other pain relief medications. Merck had no reasonable grounds to believe that these representations were true. Merck purposefully misrepresented, understated, and otherwise downplayed the serious health hazards and risks associated with Vioxx.

60. Merck's false and misleading promotion induced the State of Montana, Montana corporations, and Montana citizens to purchase Vioxx in many instances where it provided no benefit over other less risky and less expensive drugs.

61. Merck's false and misleading promotion persuaded Montana doctors to prescribe Vioxx in many instances where they would not have done so if Merck had provided them with complete and accurate information it knew about the efficacy and cardiovascular risks of Vioxx.

62. Merck's misleading and false advertisements, promotional materials, and public statements were extremely successful in building the market for Vioxx. It contributed to Vioxx reaching $2 billion in sales faster than any drug in Merck's history. Vioxx sales in 2003 alone were $2.5 billion.

63. Merck estimates that there were 105 million U.S. prescriptions written for Vioxx from May 1999 through August 2004. Based on this, Merck estimates that 20 million people have taken Vioxx in the United States since 1999.

COUNT I

The Montana Food, Drug, and Cosmetic Act: False and Misleading Advertising

64. Since 1947, the sale of drugs within Montana has been regulated by the Montana Food, Drug, and Cosmetic Act (Montana FDCA), Mont. Code Ann.§50-31-101, et seq.

65. The Montana FDCA prohibits false or misleading advertising of drugs within the State. Mont. Code Ann.§50-31,501(1,5). A drug advertisement is "deemed to be false if it is false or misleading in any particular." Mont. Code Ann.§50-31-107(1). A drug advertisement is also deemed to be misleading if it fails to reveal material facts about the consequences which may result from using the drug in the manner in which the advertisement suggests that it be used. Mont. Code Ann.§50-31-107(2).

66. The Montana Legislature has charged the Attorney General with the duty to bring appropriate proceedings in court to remedy violations of the Montana FDCA. Mont. Code Ann.§50-31-505.

67. In violation of the Montana FDCA, Merck's advertisements made false and misleading claims to doctors and the public in Montana about the effectiveness of Vioxx.

68. As a result of Merck's violation of the Montana FDCA, the State and its citizens, corporations, and other business entities have been damaged and are entitled to all the remedies and damages provided by law.

COUNT II

Deceit

69. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

70. In Merck's advertising and promotional materials, in its marketing tactics in face-to-face meetings with doctors, in its press releases, and in its public advertisements, Merck made suggestions of fact that Merck knew were not true. Such conduct constitutes deceit under Mont. Code Ann.§27-1-712.

71. Merck, in its face-to-face meetings with doctors, in its press releases, and in

public advertisements, suppressed facts about the cardiovascular dangers of Vioxx such that Montana doctors and the public were misled about its dangers. Such conduct constitutes deceit under Mont. Code Ann.§27-1-712.

72. As a result of Merck's violation of Mont. Code Ann.§27-1-712, the State and its citizens, corporations, and other business entities have been damaged and are entitled to all the remedies and damages provided by law.

COUNT III

Unfair Trade Practices and Consumer Protection Act Claim

73. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

74. In the course of business, Merck misrepresented and/or omitted material facts about the safety and effectiveness of Vioxx. Merck misleadingly claimed that Vioxx was safe and was as, or more, effective than traditional NSAIDs in treating chronic pain, that it did not cause or contribute to any cardiovascular problem greater than any other NSAIDs, and that Vioxx use should not be limited to patients with gastrointestinal problems who could not use other NSAIDs.

75. Merck systematically suppressed and concealed material information it developed or otherwise knew about the adverse cardiovascular effects of Vioxx and engaged in a mis-information and dis-information campaign to conceal the truth.

76. Merck systematically sought to discredit or cast doubt upon scientific studies and reports and the work of scientists which concluded that Vioxx caused or contributed to adverse cardiovascular effects.

77. Merck systematically engaged in a false and misleading marketing and advertising campaign to over-promote the use of Vioxx.

78. Merck's conduct, as described above, constitutes unfair and deceptive practices in violation of Mont. Code Ann. § 30-14-103.

79. As consequence of Merck's violation of Mont. Code Ann.§30-14-103, the State, its citizens, corporations, and business entities have been injured and suffered damages and are, therefore, entitled to all the damages and remedies provided by law.

COUNT IV

Unjust Enrichment and Restitution

80. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

81. Merck engaged in a systematic campaign to over-promote the use of Vioxx, claiming it was safe from any adverse cardiovascular effects and was as, or more, effective than traditional, significantly less expensive NSAIDs for treating pain and inflammation.

82. Merck knew that Vioxx causes or contributes to cardiovascular disease and myocardial infarction in users and is no more effective than much cheaper and safer non-steriodal, anti-inflammatory drugs.

83. Merck had a duty to the State Montana and to the citizens, corporations, and business entities of the State to disclose all material facts about its products and to refrain from over-promoting or falsely promoting its products as safe and more effective than traditional non-steriodal, anti-inflammatory drugs when it knew that was not true.

84. As a result of Merck's breach of this duty and the misleading suppression of the truth about Vioxx, Merck has sold millions of dollars of unnecessary and over-priced Vioxx to the State of Montana and its citizens, which likely caused adverse cardiovascular effects to the citizens of the State of Montana.

85. Merck has been unjustly enriched by its false, deceitful, and misleading conduct to the extent that the citizens of the State of Montana and the State of Montana have unknowingly paid excessive costs for Vioxx when they could have purchased significantly less expensive traditional pharmaceuticals that would have been equally effective and without the severe cardiovascular risks of Vioxx.

86. As a result of Merck's conduct, the State of Montana and its citizens have suffered substantial economic damages and are entitled to damages and all other available remedies.

WHEREFORE, the State of Montana, by and through Attorney General Mike McGrath, prays as follows:

1. That the Court adjudge and decree that Merck has engaged in the conduct

alleged herein.

2. That the Court adjudge and decree that Merck's advertising and promotion of Vioxx was false and misleading in violation of the Montana FDCA.

3. That the Court adjudge and decree that Merck violated Mont. Code Ann. §27-1-712 and that the State of Montana and its citizens were damaged thereby.

4. That the Court adjudge and degree that such conduct is unlawful and in violation of Mont. Code Ann. § 30-14-103.

5. That the Court, pursuant to Mont. Code Ann. § 30-14-142, assess civil penalties of $10,000.00 against Merck for each violation of Mont. Code Ann. § 30-14-103 complained of herein.

6. That the Court, pursuant to Mont. Code Ann. § 30-14-131, enter an order restoring to the State and to the citizens of the State all monies acquired by Merck by means of its unlawful practices.

7. That the Court order Merck to pay restitution which would restore the State of Montana and the citizens of the State of Montana the financial position that they would have enjoyed absent Merck's false representations and over-promotion of Vioxx.

8. That the Court order Merck to disgorge all unjust profits from the sale of Vioxx to the citizens of the State of Montana and the State of Montana.

9. That the Court award the State of Montana its attorneys fees and costs.

10. That the Court order such other and further relief as the Court deems just, necessary, and appropriate.

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Dated this 23d day of December, 2005.

MIKE McGRATH
Attorney General
PAMELA D. BUCY
Assistant Attorney General
P.O. Box 201401
Helena, MT 59620-1401
Tel.: 406-444-2026

BY: _____
E. CRAIG DAUE
Special Assistant Attorney General
BUXBAUM, DAUE & FITZPATRICK, PLLC
P.O. Box 8209
Missoula, MT 59807
Tel.: 406-327-8677

BY: _____
WILLIAM A. ROSSBACH
Special Assistant Attorney General
ROSSBACH HART BECHTOLD, PC
401 North Washington, Box 8988
Missoula, MT 59807
Tel.: 406-543-5156